COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 05-02-2004
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NOT FOR PUBLICATION

COMMISSION DECISION

of 05-02-2004

amending the marketing authorisation for "PegIntron - Peginterferon alfa-2b", a medicinal product for human use, granted by Decision C(2000)1407

(Text with EEA relevance)

ONLY THE FRENCH AND THE DUTCH TEXTS ARE AUTHENTIC

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1],

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular Article 8(3) thereof,

Having regard to the application submitted by Schering Plough Europe on 19 September 2003 under Article 6(1) of Commission Regulation (EEC) No 542/95,

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[3], and in particular Article 6(10) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products, formulated by the Committee for Proprietary Medicinal Products on 20 November 2003,

Whereas:

(1) An examination of the variations to the terms of the marketing authorisation for the medicinal product "PegIntron - Peginterferon alfa-2b", entered in the Community register of medicinal products under Nos EU/1/00/131/001-050 and authorised by Commission Decision C(2000)1407 of 25 May 2000, has shown that the product still complies with the requirements set out in Directive

[1] OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).
[2] OJ L 55, 11.3.1995, p. 15, as amended by Regulation (EC) No 1069/98 (OJ L 153, 27.5.1998, p. 11).
[3] OJ L 159, 27.6.2003, p. 24.

2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(2) The application to modify the authorisation and to amend Decision C(2000)1407 accordingly should be accepted.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000)1407 is amended as follows:

1. Annex I is replaced by the text set out in Annex I to this Decision;

2. Annex III B is replaced by the text set out in Annex II to this Decision.

Article 2

This Decision is addressed to Schering Plough Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique – Stallestraat, 73 – 1180 Brussel, België.

Done at Brussels, 05-02-2004

For the Commission
Erkki LIIKANEN
Member of the Commission

[4] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2003/63/EC (OJ L 159, 27.6.2003, p. 46).